JUL - 7 2008

K081043

NxStage Medical, Inc.
Leak Detection Sensor and Tray
Traditional 510(k) Premarket Notification

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92.

A. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	439 South Union Street, 5th Floor Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Regulatory Affairs Associate
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 439 South Union St. 5th Floor Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075

B. Device Name:

Trade/Proprietary Name:	NxStage Leak Detection Sensor and Tray
Common/Usual Name:	Leak Detector
Classification Name:	Hemodialysis System and Accessories
Regulation Number:	876.5820
Product Code:	KOC
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

C. Substantial Equivalence/Predicate Devices:

The NxStage leak detection sensor and tray are substantially equivalent to:

Device Name	Manufacturer	510(K)
PureFlow SL	NxStage Medical, Inc.	K043436
Aksys PHD Personal Hemodialysis System	Aksys, LTD	K010131
Nytone Enuretic Alarm Bedwetting Device	Nytone Medical	K844866

D. Device Description/Indications for Use:

The NxStage leak detection sensor and tray is designed for use with the NxStage System One. The plastic tray and leak detection sensor are external devices that are not connected to the NxStage System One. The tray fits under the door area of the NxStage System One cycler. The tray includes a molded area on the left-hand side that holds a commercially available leak detection sensor.

Indications for use:

The leak detection sensor and tray provide a means of detecting fluid leaks when used as an accessory to the NxStage System One.

E. Technological Characteristics:

The proposed device has similar technological characteristics and design features as compared to the predicate devices.

F. Summary of Non-Clinical Test/Performance Testing - Bench

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation testing was conducted to characterize performance of the proposed leak detection sensor and tray. Results of this testing have documented that the proposed leak detection sensor and tray is substantially equivalent to the predicate devices and is suitable for the labeled indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 7 2008

Ms. Mary Lou Stroumbos
Regulatory Affairs Associate
NxStage Medical, Incorporated
439 South Union Street, 5th Floor
LAWRENCE MA 01843

Re: K081043
Trade/Device Name: NxStage® System One™ Leak Detection Sensor and Tray Accessory Kit
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: April 10, 2008
Received: April 14, 2008

Dear Ms. Stroumbos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081043

Device Name: NxStage System One Leak Detection Sensor and Tray Accessory Kit.

Indications for Use: The leak detection sensor and tray provide a means of detecting fluid leaks when used as an accessory to the NxStage System One.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081043